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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,338	09/17/2003	Michael P. Dwyer	OC01628K	4130

24265 7590 09/10/2004

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

HUANG, EVELYN MEI

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/664,338

Applicant(s)

DWYER ET AL.

Examiner

Evelyn Huang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 20-28 and 30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 19 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 10-17, 29 and 31 is/are rejected.
- 7) ☒ Claim(s) 5, 7-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-31 are pending.

#### ***Election/Restrictions***

2. In response to the restriction requirement mailed on 6-9-2004, Applicants have elected with traverse the Group I invention, claims 1-19, 29, 31. Claims of Groups II-IV are withdrawn from further consideration as being drawn to the non-elected invention.

Applicant argues that a search for the Group I compound, the Group II-III methods and the Group IV composition can be carried out simultaneously.

On the contrary, the compound of Group I has utility other than the disclosed methods of inhibiting a cyclin dependent kinase, and the treatment of diseases dependent thereof, for example, it can be used as a bone resorption inhibitor (Kawai, WO 96/34866, PTO-1449) or as a bradykinin antagonist (Oku, 5574042). These references anticipating the Group I compound would not render obvious the other groups of invention. The search therefore is not co-extensive and is burdensome. The restriction as indicated is therefore proper.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 2, definition of R5, 'R5 is' is repeated twice.
- b. Claim 10, H has no antecedent basis in the base claim 2.

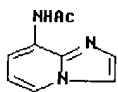
***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

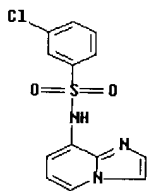
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hand et al. (J. Org. Chem. 1978, 43(14): 2900-6, PTO-1449). Compound 18 in purified form with the following structure is encompassed by the instant claims wherein R is C(O)R7 and R7 being alkyl.

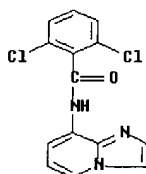


6. Claims 1-4, 10, 12-17, 29, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshino (EP 673937, PTO-1449). Compound of Example 20 in purified form with the following structure, and the composition thereof, are encompassed by the instant claims wherein R is 3-chloro substituted phenylsulfonyl.

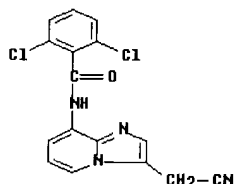


7. Claims 1-4, 10-17, 29, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshino (EP 673937, PTO-1449). Compound with the following structure in the purified form, and the composition thereof, are encompassed by the instant claims 1-4, 10, 12-17, 29, 31 wherein R is benzoyl substituted with dichloro, R2, R3, R4, R11 are H.

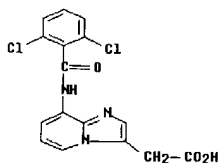
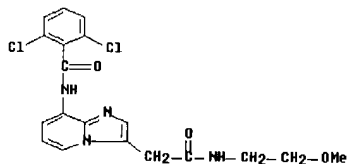
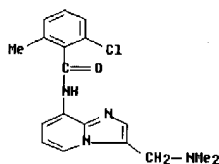
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Compound with the following structure in the purified form, and the composition thereof, are encompassed by the instant claims 1-4, 12-17, 29, 31 wherein R is benzoyl substituted with dichloro, R2 is CN substituted alkyl, R3, R4, R11 are H.

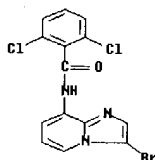


Compounds with the following structure in the purified form, and the composition thereof, are encompassed by the instant claims 1, 29, 31 wherein R is benzoyl substituted with dichloro, R2 is substituted alkyl, R3, R4, R11 are H.



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Compound with the following structure in the purified form, and the composition thereof, are encompassed by the instant claims 1-4, 10-17, 29, 31 wherein R is benzoyl substituted with dichloro, R2 is Br, R3, R4, R11 are H.



### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 6, 10, 12-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Basso et al. (Tetrahedron. 2002, 58:4445-4450, published on May 27, 2002, PTO-1449). The compound 16 on page 4447 is encompassed by the instant claims.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 10-17, 29, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oku (5574042).

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Oku generically discloses a bradykinin antagonist compound (column 1), and the composition thereof, which encompasses the instant. A specific example, 3-chloro-8-(2,6-dichlorobenzylamino 2, 7-dimethyl-imidazo[1,2-a]pyridine, is described (Example 3, column 59, compound (7) ).

Oku's example has a 2-methyl whereas the compound of instant claim 6 has a hydrogen.

The methyl is the next adjacent homolog of hydrogen. Furthermore, Oku expressly teaches that methyl and hydrogen are optional choices (column 1, lines 52-53, definition of R2).

At the time of the invention, one of ordinary skill in the art would be motivated to replace the methyl with the alternative hydrogen to arrive at the instant invention with the reasonable expectation of obtaining an additional bradykinin antagonist compound since Oku had clearly taught that any species within the disclosed genus would be useful as a bradykinin antagonist.<sup>9</sup>

#### *Allowable Subject Matter*

10. Claims 5, 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

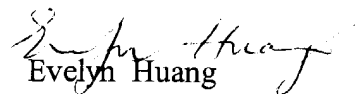
Claims 18, 19 are allowed. The instant compound with an aryl or heterocyclyl ring as R3, a pyridinylmethyl or pyrimidinylmethyl, thienylmethyl or furanyl as R is not anticipated by the prior art of record. Motivation to modify the prior art of record via multiple changes to arrive at the instant is lacking.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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